March 23, 2017

Idaho Medicaid
Pharmacy & Therapeutics Committee
Attention: Tami Eide, Pharm.D.
3232 Elder Street
Boise, Idaho 83705

Dear Ms. Eide:

On behalf of patients and families with cystic fibrosis (CF) living in Idaho, we write to urge the Idaho Medicaid program to include all FDA-approved pancreatic enzyme products for the treatment of CF patients on the preferred drug list (PDL).

About the CF Foundation
Cystic fibrosis is caused by genetic mutations that result in the malfunction of a protein known as the cystic fibrosis transmembrane conductance regulator (*CFTR*). Decreased CFTR function causes irreversible organ damage and the associated symptoms of cystic fibrosis and leads to early death, usually by respiratory failure. As the world's leader in the search for a cure for CF and an organization dedicated to ensuring access to high quality, specialized CF care, the Cystic Fibrosis Foundation accredits 123 care centers, including 2 in Idaho, and 55 affiliate programs nationally that provide multidisciplinary, patient-centered care in accordance with systematically reviewed, data-driven clinical practice guidelines. Treatment options for this rare, life-threatening disease are extremely limited.

About Pancreatic Enzyme Replacement Therapy
Open access to pancreatic enzymes is critical, as approximately 90 percent of CF patients have pancreatic insufficiency. Cystic fibrosis is a multi-system disease that causes the ducts in the pancreas to become clogged with thick, sticky mucus that blocks natural enzymes from reaching food in the small intestine. Decreased pancreatic function leads to malabsorption of calories and nutrients, and therefore, difficulty with growth and weight gain. Patients with pancreatic insufficiency require lifelong pancreatic enzyme replacement therapy (PERT) with each meal and snack to maintain adequate nutrition and prevent abdominal distress. This is a life-sustaining therapy — nutritional status is closely linked to pulmonary function and survival.

Selecting one enzyme as a preferred product neglects to account for the variable clinical responses of CF patients to pancreatic enzyme therapies and more importantly, requires patients to fail one therapy prior to allowing them to use another. Nutritional failure of any type for CF patients places them at risk for long-term health consequences.

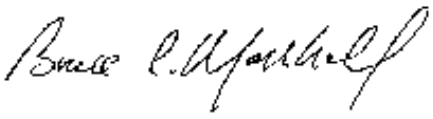
Although the drug substance is the same, the dissolution properties of the PERTs are not identical. The differences in enteric coating, coating process, and size of each FDA-approved product affects a patient's ability to absorb nutrients. The degree of acidification of the GI tract in each CF patient also varies, causing some patients to have a better clinical response to one product over another. Failure of pancreatic enzyme therapy may be due to patient and product differences that can only be determined by an experienced clinician who has close follow up with each patient.

Policy Recommendation
Limiting patient choice for enzymes can greatly impact the health of people with cystic fibrosis who require them for optimal treatment. These therapies are an important part of standard CF care.

We urge you to provide access to all pancreatic enzyme therapies for people with cystic fibrosis as prescribed by their physician.

Please contact Jackie Erdo, MPH, Manager of Access Policy and Innovation, at jerdo@cff.org or 301-841-2628 with any further questions. We look forward to working with you on this important issue.

Sincerely,



Bruce C. Marshall, MD
Senior Vice President of Clinical Affairs

Lisa Feng, MPH
Senior Director, Access Policy & Innovation